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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,386	03/19/2004	Michael L. Garrison	1-37234	7250

42715 7590 06/06/2006

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EXAMINER	
YABUT, DIANE D	
ART UNIT	**PAPER NUMBER**
3734	

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,386	GARRISON ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *5-7,15-17 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8-14 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/27/04; 6/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: IDS (cont'd): 8/30/04; 10/1/04; 3/24/05.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species 1 in the reply filed on 02 May 2006 is acknowledged. The traversal is on the ground(s) that the various species reflect various alternative structures used to space a portion of the elongate member away from a body vessel wall during deployment of an expandable intraluminal medical device, and would require a single search and not impose an unduly burdensome requirement on the Examiner. This is not found persuasive because each of the species is patentably distinct from the other and do not overlap in scope are and are not obvious variants of each other. Therefore these alternative structures would require more than a single search and impose a burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 5-7, 15-17, and 19-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Species 2-7, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02 May 2006.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 27 May 2004 is acknowledged. In addition, the information disclosure statements submitted on 07 June 2004, 30 August 2004, 01 October 2004, and 24 March 2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner. However, the non-patent literature disclosed was not considered by the examiner of 24 March 2005, and applicant should resubmit the documents listed.

Specification

4. The abstract of the disclosure is objected to because it should provide more detail in terms of the structures used for spacing the portion of the delivery device from the vessel wall and the steps of the method for spacing and deployment of the expandable intraluminal medical device. Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: A detailed description of Figure 7 is missing. Applicant should mention Figure 7 in the disclosure with detail.

Appropriate correction is required.

Claim Objections

6. Claims 2-4, 8-12, 14, and 18 are objected to because of the following informalities: Claims 2-4 and Claims 8-12 are dependent claims (of independent Claim 1) and read "A method for" and should instead read --**The** method for--. Claims 14 and 18 are also dependent claims (of independent Claim 13) and read "A delivery system for" and should instead read --**The** delivery system for--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kirkman** (U.S. Patent No. **6,071,263**).

Claim 1: Kirkman discloses a method for delivering and deploying an expandable intraluminal device, providing a delivery system comprising an elongate member **4** having proximal and distal ends, and the expandable intraluminal medical device **154** circumferentially disposed about a portion of the elongate member **4** (Figure 10A and 10B). The distal end of the elongate member **4** is inserted into a body vessel, and the distal end of the elongate member **4** is advanced **4** through the body vessel to the desired point of treatment. A portion of the elongate member is spaced from a wall

surface of the blood vessel, and the expandable intraluminal medical device is deployed from the elongate member. Lastly, the elongate member is withdrawn from the body vessel (col. 12, lines 26-28 and col. 13, lines 5-50).

Claim 2: Kirkman also discloses that the step of spacing a portion of the elongate member from a wall surface of the body vessel comprises spacing a portion of the elongate member that includes the expandable intraluminal device **154**, which lies at the catheter tip **8** (col. 12, lines 55-59).

Claim 3: Kirkman discloses that the elongate member **2** defines a lumen and the delivery system further comprises an ancillary delivery device **9** having a means for spacing a portion of the elongate member **2** from a wall surface of a body vessel (col. 3, lines 50-53 and col. 6, lines 43-47).

Claim 4: Kirkman discloses the means for spacing comprising a basket **9** formed from four wires **12** and having expanded and collapsed configurations (Figures 2A-2B and col. 8, lines 15-19).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **St. Germain et al.** (U.S. Patent No **5,534,007**).

Claim 8: Kirkman discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member and movable along the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device

St. Germain et al. teaches deployment catheter for an expandable intraluminal device that comprises a sheath **40** that is circumferentially disposed about and movable along an elongate member **5**, and the step of deploying the expandable intraluminal device **35** comprises retracting the sheath **40** from a position about the expandable intraluminal medical device **35** (Figure 1 and col. 3, lines 27-36). St. Germain et al. teaches that the use of the sheath **40** retains the expandable intraluminal device **35** and protects the vessel wall (col. 3, lines 36-38). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a sheath that is circumferentially disposed about the elongate member and retracting the sheath in the

step of deploying the expandable intraluminal device, as taught by St. Germain et al., to Kirkman in order to retain the expandable intraluminal device before deployment and to protect the vessel wall from injury.

Claim 9: Kirkman discloses the elongate member **2** defining a lumen and the delivery system further comprising an ancillary delivery device **9** disposed within the lumen, the ancillary delivery device having a means for spacing a portion of the elongate member from a wall surface of a body vessel (Figures 2A and 2B).

Claims 10-11: Kirkman discloses the step of spacing a portion of the elongate member from a wall surface of the body vessel which comprises activating the means for spacing, which includes retracting the sheath from a position about the means for spacing (col. 8, lines 10-19).

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kirkman** (U.S. Patent No. **6,071,263**) in view of **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 12: Kirkman discloses the claimed steps except for the expandable intraluminal medical device comprising a prosthetic venous valve

Pavcnik et al. teaches an intraluminal venous valve **43** that is deployed within the blood vessel and exerts force against the wall of the vessel and provides a partial seal against the wall, while having expandable and collapsible features (Figures 48-49 and page 1, paragraph 6, page 6, paragraph 68, and page 10, paragraph 87). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a

prosthetic venous valve device, as taught by Pavcnik et al., to the device of Kirkman, since it was known in the art that the delivery system may deploy any suitable expandable intraluminal medical device, such as a prosthetic venous valve.

12. Claims 13,14, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Levine et al.** (U.S. Pub. No. **20040087965**) in view of **Kirkman** (U.S. Patent No. **6,071,263**) and **Pavcnik et al.** (U.S. Pub. No. **20010039450**).

Claim 13: Levine et al. discloses a delivery system comprising an elongate member **118** having proximal and distal ends and defining a first lumen, an expandable intraluminal medical device **108**, a sheath **1000** circumferentially disposed about the elongate member and the expandable intraluminal device, the sheath being movable along the elongate member **118**, and an ancillary delivery device **106** disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations, wherein the basket is in the collapsed configuration when disposed in the first lumen and is in the expanded configuration when not disposed in the first lumen (Figures 3, 4F, and 10). Levine et al. discloses the claimed device except for the expandable intraluminal medical device **108** being circumferentially disposed about a portion of the elongate member **118**.

Kirkman teaches an expandable intraluminal device **154** which is circumferentially disposed about the distal portion of elongate member **4** (Figure 10A). It would have been obvious to one of ordinary skill to provide the expandable intraluminal device **154** circumferentially disposed about the elongate member **4**, as

taught by Kirkman, to Levine et al. since it was known in the art that devices that are delivered and deployed must be attached to the delivery device (in this case the delivery device is a catheter), and are commonly circumferentially disposed about the delivery device.

Claim 14: Levine et al. discloses the wire members **104** comprising flat wire (page 3, paragraph 37).

Claim 18: Levine et al. discloses the claimed device except for the expandable intraluminal device comprising a prosthetic venous valve. Pavcnik et al. discloses an expandable intraluminal device comprising a prosthetic venous valve. See explanation for Claim 12 above in paragraph 18.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Majercak** (U.S. Patent No. **6,932,829**) discloses a centering catheter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
PRIMARY EXAMINER